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PEARNE & GORDON LLP
1801 EAST 9TH STREET
SUITE 1200
CLEVELAND, OH 44114-3108

EXAMINER	
SASAN, ARADHANA	
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1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,240	CAVASSINI ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks filed on 05/08/08 are acknowledged.

2. Claims 1-59 are included in the prosecution.

Response to Arguments

Rejection of claims 1-8, 22-40 and 46-56 under 35 USC § 103(a)

3. Applicant's arguments, see Pages 2-5, filed 05/08/08, with respect to the following rejections have been fully considered but are not persuasive.

- Rejection of claims 1-8, 22-40 and 46-56 under 35 USC § 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890).
- Rejection of claims 9-14, 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Richardson (US 6,797,291).
- Rejection of claims 15-19, and 41-42, are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Brommelsiek et al. (US 5,766,668).
- Rejection of claims 20-21, 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Richardson (US 6,797,291) and Brommelsiek et al. (US 5,766,668).

Applicant argues that Iijima does not teach the overcoating of choline chloride comprising an outer layer of carnauba wax and an inner layer of a hydrophobic substance.

This is not persuasive because Iijima teaches overcoating by carnauba (Col. 3, lines 34-40 and lines 50-56). The limitation of the inner layer of a hydrophobic substance is also taught by the hydrophobic agents such as hydrogenated palm oil taught by Iijima.

Applicant argues that the combination of the teachings of Iijima, Riga and optionally others is not obvious to the person skilled in the art. Applicant states that first reason is that the person skilled in the art is not motivated to combine the teachings of Iijima with Riga to achieve a better retardant for a ruminant digestive system. Applicant argues that Riga teaches the use of retardant particle for a monogastric animal. Applicant presents a copy of page 23 of B. A. Dehority, Gross anatomy, physiology and environment of the ruminant stomach, in Rumen Microbiology, Nottingham, NUP, 2003, where one can see that it is taught that the "Rumen solids turnover times in cattle have been observed to range from 1.3 to 3.7 days, with most values averaging about 2.1 to 2.7 days or 50-60 hours." (ref. page 23, third paragraph). Applicant argues that the conditions of the ruminant digestive system are much more stringent and complicated than that of the monogastric animal. The Applicant argues that there is nothing in Riga that suggests or motivates the person skilled in the art to transfer the teaching of using carnauba wax as an outside layer of retardant in a particle for use in monogastric

animals to polygastric animals, particularly when the other retardant layer suggested does not work in ruminant animals.

This is not persuasive because instant claims are drawn to a composition. Iijima art teaches a composition of choline chloride in the core, coated with hydrophobic materials and including a hydrophobic overcoating of agents including carnauba wax. Riga provides the teaching of specifically overcoating a first layer by an outer layer of a carnauba wax retardant. Applicant's arguments regarding the difference between the use of the composition for monogastric animals vs. polygastric animals are not persuasive because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since the primary reference Iijima teaches a choline composition for a ruminant, the combination with Riga would be obvious to a person having ordinary skill in the art since structurally all the limitations of the claims are taught.

Applicant argues that the second reason that the invention according to the present application is not obvious over the combination of the teachings of Iijima with Riga is that the particles according to the invention have to be stable, as well as being rumen stable and post ruminally effective. Applicant states that this second advantageous and unexpected effect is not taught, nor suggested in either Riga or Iijima.

This is not persuasive because Iijima points out the deliquescent nature of choline and the need to make a granular rumen-bypass agent which is not solubilized or decomposed in the rumen and is dissolved and absorbed in the abomasum and downstream (Col. 1, lines 19-47). Therefore, one with ordinary skill in the art would know that the granular compositions taught by Iijima are rumen stable (not dissolved or decomposed in the rumen) in order to effectively reach the abomasum.

Therefore, the rejection of 01/15/08 is maintained.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-8, 22-40 and 46-56 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890).

The claimed invention is a composition of matter comprising particles. Each particle comprises a core which contains choline chloride in the form of a dry, crystalline powder and a protective coating surrounding the core. The protective coating comprises an outer, continuous layer mainly consisting of carnauba wax, and an inner continuous layer consisting of a hydrophobic substance. Feed pellets, premix for feed, and mash feed containing the composition are also claimed.

Iijima teaches a granular composition containing choline for a ruminant. The granular composition is "capable of reaching an abomasum and downstream thereof substantially in the form of granules, without easily dissolved or decomposed in the rumen" (Col. 2, lines 3-9). Choline chloride is a preferable choline derivative (Col. 2, lines 45-46). Hydrophobic agents such as hydrogenated palm oil, hydrogenated soybean oil, stearic acid, and carnauba wax are disclosed as binders and overcoating agents for the granules (Col. 3, lines 34-40 and lines 50-56). It is also disclosed that the granular composition may contain "any ingredients conventionally used in the animal feed, especially for a ruminant" (Col. 4, lines 9-15). The choline chloride is powdered since the particle size is disclosed. "Cholines having an average particle size of 100μm or less ... and a maximum particle size of 150μm or less ... are granulated with excipients and hydrophobic binders" (Col. 4, lines 18-27). The particle size of choline chloride is achieved by grinding in an appropriate grinder (Col. 4, lines 42-46). Granulation methods such as fluidized granulation and agitation granulation are disclosed (Col. 5, lines 44-53). "... When the agitation granulation is used, relatively spherical or round granulated particles, which are suitable for subsequent coating, can be advantageously obtained ... the fluidizable binder is migrated to the surface of the granules during the granulation to form a surface layer. As a result, the cholines and other powder to be protected is relatively located in the inside portion of the granules" (Col. 5, lines 54-64). The resultant granules have a particle size of 0.5 to 2.5mm (Col. 6, lines 49-51). The choline granules "are overcoated with a thin film by adding 20 to 40 parts, preferably 20 to 30 parts by weight, of a molten mixture, ... of a hydrophobic

overcoating agent and a solubility modifier ..." (Col. 6, line 67 to Col. 7, line 6). "When the dissolution test of Example 1 was carried out with respect to the inner granules of Example 1 in which the overcoating was not applied, the dissolution rate in the rumen solution was 99%. As a result, the choline chloride was substantially completely dissolved in a rumen corresponding solution. Thus, when the coating is not applied, the desired resistance is not obtained" (Col. 9, lines 44-52).

Iijima does not expressly teach the overcoating of the choline chloride comprising an outer layer of carnauba wax and an inner layer of a hydrophobic substance.

Riga teaches a composition of enterosoluble units where a first layer of retardation is achieved by a polymer coating (of ethyl cellulose as the insoluble polymer) and "in the second step Carnauba wax is introduced in a ratio (wt/wt) of 1/0.47 -1/0.53 to the first retarder" (Col. 9, lines 15-22). The carnauba wax is used as a second retardant for the granule coating.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, and specifically overcoating the first layer by an outer or second layer of retardant by using carnauba wax, as suggested by Riga, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Riga teaches prolonged release by using the carnauba wax as a second coating for the active containing granule (Col. 33, lines 38-50). Moreover, one skilled in the art would

modify the components of the layers according to the desired stability of the core. Iijima teaches, "the binder and the overcoating agent may be the same or different, but the use of the same or similar substances is preferable because the good coating can be obtained when the compatibility of the binder with the overcoating agent is good" (Col. 7, lines 47-51). One skilled in the art would know the compatibility of hydrophobic components of the overcoating such as carnauba wax and hydrogenated oils. Moreover, one skilled in the art would know that carnauba wax melts at a higher temperature than hydrogenated vegetable oils and would use that as the outer layer or coating in order to further stabilize the coated granule in the rumen.

Regarding instant claim 1, the limitations of dry, crystalline choline chloride, coated with carnauba wax and a hydrophobic substance that is ruminally protected would have been obvious to one skilled in the art over the teaching of Iijima (Col. 4, lines 18-27).

Regarding instant claims 2-4, the limitation of micronized choline chloride would have been obvious to one skilled in the art over the Iijima teaching of ground choline chloride and particle size of 150μm (Col. 4, lines 18-27). One skilled in the art would grind the choline chloride and vary the particle size in the composition in order to optimize the rumen protection.

Regarding instant claims 5-6, the limitation of choline chloride percentage in the core would have been obvious to one skilled in the art over the Iijima teaching of choline chloride coated core (Col. 6, line 67 to Col. 7, line 6). One skilled in the art would vary the amount of choline chloride in the core during routine experimentation, in order to

optimize the efficacy of the coated composition. The recited percentages are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 7-8, and 39-40, the limitations of the core comprising additional substance, particularly a flow modifier, would have been obvious to one skilled in the art over the teaching of Iijima where talc is used in the core composition along with choline chloride (Col. 8, Example 1 Granulation, lines 32-36). Talc is known as a flow modifier in the art.

Regarding instant claims 22-26, the percentages of the additional substances in the core would have been obvious to one skilled in the art over the teaching of Iijima (Col. 8, Example 1 Granulation, lines 32-36). The percentages are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 27-28, the percentages of the core weight with respect to the whole particle would have been obvious to one skilled in the art over the teaching of Iijima (Col. 8, Example 1 Granulation, lines 32-36). One skilled in the art would vary the percentage of core with respect to the coatings during the process of routine optimization.

Regarding instant claims 29-30, the percentages of the carnauba with respect to the outer layer would have been obvious to one skilled in the art over the teaching of Riga (Col. 9, lines 15-22). One skilled in the art would vary the percentage of carnauba wax with respect to the outer layer during the process of routine optimization.

Regarding instant claims 31-38, the limitations a rigidity-controlling agent mixed with carnauba wax would have been obvious to one skilled in the art over the teaching of Iijima. Iijima teaches hydrogenated palm oil, hydrogenated bean oil, hydrogenated coconut oil, stearic acid, carnauba wax etc. as hydrophobic binders (Col. 3, lines 34-40). One skilled in the art would find it obvious to combine the lower melting hydrogenated vegetable oils with the higher melting carnauba wax in order to control the rigidity of the coating layer. One skilled in the art would know that the rigidity of the outer coating layer is primarily provided by the higher melting carnauba wax, and by adding a lower melting point component (such as a hydrogenated vegetable oil) would modify the rigidity of the outer coating layer. The percentages of the rigidity-controlling agent would be obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 46-49, the limitations of outer coating percentage and inner coating percentage would have been obvious to one skilled in the art over the granule coating with carnauba wax taught by Riga (Col. 33, lines 47-49) and because the percentage of the inner and outer coatings would be varied during the process of routine optimization of stabilizing choline chloride in the rumen.

Regarding instant claims 50-54, the limitations of lipids as the hydrophobic substances would have been obvious to one skilled in the art given the teaching of hydrogenated oils and stearic acid by Iijima (Col. 3, lines 34-40 and lines 50-56).

Regarding instant claims 55-56, the percentage of the protective coating with respect to the whole particle would have been obvious to one skilled in the art over the overcoating "with a thin film by adding 20 to 40 parts, preferably 20 to 30 parts by

weight, of a molten mixture, ... of a hydrophobic overcoating agent and a solubility modifier ..." as taught by Iijima (Col. 6, line 67 to Col. 7, line 6) and because the percentage of the protective coating would be varied during the process of routine optimization of stabilizing choline chloride in the rumen.

6. Claims 9-14 and 57-59 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Richardson (US 6,797,291).

The teachings of Iijima and Riga are stated above.

Iijima and Riga do not expressly teach silicates as flow modifiers.

Richardson teaches compositions for stabilizing a hygroscopic bioactive substance, such as choline chloride and also providing adequate rumen protection in ruminant feeds (Abstract). The choline chloride is encapsulated "with a lipid coating in an amount sufficient to retain at least about 60 wt % of the hygroscopic ingredient after the encapsulated ingredient is combined with the moist composition for a time period of at least about 1 day; and ... combining the encapsulated hygroscopic ingredient with the moist composition" (Col. 3, lines 41-47). The hygroscopic ingredient can be choline chloride (Col. 3, line 48). The moist composition is a ruminant feed (Col. 3, lines 54-55). Hydrogenated vegetable (soybean) oil is the preferred lipid for coating (Col. 3, lines 64-65). Hydrogenated vegetable oil can be mixed with lesser amounts of wax (Col. 3, line 66 to Col. 4, line 5). It is further disclosed that, "skilled practitioners also recognize that flow agents, such as finely-divided silica, can be admixed with the particles of the invention to facilitate handling" (Col. 10, lines 11-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, specifically use carnauba wax as a second coating layer on the core, as suggested by Riga, and further use silica as the flow agent, as taught by Richardson, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Richardson teaches, "skilled practitioners also recognize that flow agents, such as finely-divided silica, can be admixed with the particles of the invention to facilitate handling" (Col. 10, lines 11-13).

Regarding instant claims 9 and 10, the limitation of aluminosilicate would have been obvious to one skilled in the art over the sodium aluminosilicate teaching of Richardson (Col. 4, lines 6-11). Richardson teaches "the encapsulates can contain additives whose role is to facilitate the implementation of the techniques for preparing these encapsulates or to improve the physicochemical characteristics ... if included, these additives generally represent only a few percent by weight of the coating" (Col. 9, lines 46-62).

Regarding instant claim 11, the flow modifiers including silica would have been obvious to one skilled in the art over the silica teaching of Richardson (Col. 10, lines 11-13).

Regarding instant claims 12-14, the percentage of flow modifier would have been obvious to one skilled in the art over the Richardson teaching that "these additives are typically added in the range of 1 to 30 percent by weight" (Col. 9, lines 61-62).

Regarding instant claims 57-59, the limitations of the composition in feed pellet, premix for feed with the composition, and mash feed with the composition would have been obvious to one skilled in the art over the Richardson teaching that the encapsulated ingredient (choline chloride) is combined with a moist composition which is a ruminant feed (Col. 3, lines 54-55).

7. Claims 15-19, and 41-42 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Brommelsiek et al. (US 5,766,668).

The teachings of Iijima and Riga are stated above.

Iijima and Riga do not expressly teach stearates as binders acting as moisture barriers in the core composition.

Brommelsiek teaches a choline feed stock precursor having greater than about 80-wt% of choline chloride, a lubricating agent, and an excipient (Abstract). Lubricants such as stearate salts are added to the spray drying system (Col. 7, lines 17-25). "The lubricant may be added during processing in concentrations which range from about 0 to 10 wt-% of the finished product ..." (Col. 7, lines 26-27). "The ratio of calcium stearate

to choline chloride may range from about 0.01 to 1 to about 0.06 to 1" (Col. 7, lines 46-49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, specifically use carnauba wax as a second coating layer on the core, as suggested by Riga, and further use lubricants such as stearate salts, as taught by Brommelsiek, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Brommelsiek teaches that inclusion of stearate salts as lubricants is "useful in producing a stable choline product ... this constituent assists in providing lubricity to the system during spray-drying and preventing deliquescence of the final composition" (Col. 4, lines 40-45). Since choline chloride is known in the art to be hygroscopic, using stearates to prevent the hygroscopic nature of the coated core of choline chloride would have been obvious to one skilled in the art. Even though Brommelsiek teaches spray drying liquid choline chloride, the end result is still a powdered choline chloride and lubricants are added to prevent deliquescence.

Regarding instant claims 15-19 and 41-42, the limitation of the binder and the percentage of binder acting as a moisture barrier in the core would have been obvious to one skilled in the art given the teaching of Brommelsiek that 0-10% of lubricant can be used in the composition (Col. 7, lines 26-27). One skilled in the art would vary the percentage during the process of routine experimentation.

8. Claims 20-21 and 43-45 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Riga et al. (US 6,174,890) and further in view of Richardson (US 6,797,291) and Brommelsiek et al. (US 5,766,668).

The teachings of Iijima, Riga and Richardson are stated above.

Iijima, Riga and Richardson do not expressly teach silicates as flow modifiers or stearates as binders acting as moisture barriers in the core composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, specifically use carnauba wax as a second coating layer on the core, as suggested by Riga, and further use silica as the flow agent, as taught by Richardson and lubricants such as stearate salts, as taught by Brommelsiek, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Richardson teaches silica as a flow agent and Brommelsiek teaches lubricants such as stearates to reduce the hygroscopic nature of encapsulated choline chloride which has an impact on ruminant feed storage and stability.

Regarding instant claims 20-21, 43-45, the limitations of percent choline chloride in the core, percent of flow modifier silica, percent of calcium stearate, percent of protective coating (outer and inner layers), and final particle size would have been obvious to one skilled given the teachings of Iijima (Col. 6, line 67 to Col. 7, line 6), Riga

(Col. 33, lines 38-50), Richardson (Col. 10, lines 11-13), and Brommelsiek (Col. 7, lines 26-27). One skilled in the art would vary the levels of the components and coatings in order to optimize the stability of the choline chloride in the rumen. The percentages and particle sizes recited are obvious variants unless there is evidence of criticality or unexpected results.

Conclusion

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615